DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852-1448

Meeting Response Memorandum

Our Reference: BN080041/0

Division of Blood Applications

TODAY'S DATE: Aug 28, 2009 **PAGES:** 4

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SUBJECT: Summary of FDA Internal Meeting

PRODUCT:

We have completed our review of your information package for a teleconference regarding potential licensing requirements for InterSol solution (Platelet Additive Solution PAS 3) and are providing the following responses to the questions you posed in the package. Although we continue to reserve Aug 31, 2009 at 2 PM EDT for a teleconference with you regarding this topic, if you find that our attached responses and advice are sufficiently clear and complete to obviate the need for further discussion, please inform us as soon as possible so that the meeting time may be cleared. Alternatively, if you have questions regarding specific responses or advice, please inform us so that the appropriate members of the review team can provide clarification during the reserved meeting time.

THANK YOU

Questions from the Sponsor/Applicant:

Licensing Requirements:

Sponsor Question #1:
We believe the requirements for licensing PAS 3 platelets should be the same as for any platelet apheresis product. Does FDA agree?

FDA Response to Sponsor Question #1:
FDA agrees.

Sponsor Question #2:
Will samples representative of the PAS 3 products be required to be submitted to CBER for evaluation prior to licensing approval?

FDA Response to sponsor Question #2:
Since the PAS 3 platelets product is a separate and distinct product, establishments should be submitting a sample representative of the PAS 3 products for evaluation, as part of the licensing application. Details of the plan will be discussed with the blood centers.

Validation Requirements:

Sponsor Question #3:
We believe that the validation requirements for PAS 3 platelets should be the same as for any platelet apheresis product. Does FDA agree?

FDA Response to sponsor Question #3:
FDA agrees. We believe that the blood centers should follow the recommended validation plans in the December 2007 Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods.

Sponsor Question #4:
Since the only change to the PAS 3 procedure is the addition of PAS 3 to the platelet product post-collection, we assume the validation will be limited to PAS 3 platelets and not include the revalidation of ----(b)(4)----------. Does FDA agree with this approach?

FDA Response to sponsor Question #4:
------(b)(4)----------

Monthly Quality Control Requirements:

Sponsor Question #5:
Since the separation is not changed by the addition of PAS 3, we believe that ---(b)(4)--- QC testing requirements specifically for PAS 3 platelets should be the same QC requirement as

platelets stored in 100% plasma to include platelet count, residual WBC count, pH and observation for aggregates. Does FDA agree with this approach?

FDA Response to sponsor Question #5:
We disagree that the -(b)(4)- QC testing requirement for the PAS 3 are the same as the QC requirement as platelets stored in 100% plasma. We believe that the blood centers should follow the recommended quality control plans in the December 2007 Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods. However, because it's a separate and distinct product than those stored in 100% plasma, the collection sites should be collecting separate -(b)(4)- QC data for PAS 3 platelets products.

Sponsor Question #6:
For blood centers that collect both PAS 3 platelets and platelets stored in plasma we believe that the total sample size of products tested for -(b)(4)- *QC will remain the same as currently tested with a combination of PAS 3 products and platelets stored in plasma being represented. Fenwal believes that these platelets should be integrated into the current process and that separate QC should not be required for PAS 3 products. Does FDA agree with this approach?*

FDA Response to sponsor Question #6:
PAS-stored apheresis platelets constitute a separate and distinct product from plasma stored apheresis platelets; therefore a separate set of QC testing, including all parameters, should be conducted on the PAS-stored platelets.

Donor Management:

Sponsor Question #7:
In a PAS 3 collection, the nominal storage fluid volume of 65% PAS 3 and 35% plasma is automatically added to the platelet product post-collection and the plasma no longer needed for storage is returned to the donor during the collection procedure. If a site elects to collect that volume of plasma, instead of returning it to the donor, and no additional plasma is collected from the donor, will the donation interval for the donor remain the same as that for a platelet donor? In other words, can the "extra" plasma from a PAS 3 procedure as compared to a 100% plasma platelet procedure be collected and processed/stored without counting that plasma toward the amount allowed before a donor is pushed into a "frequent plasma donor" program?

FDA Response to sponsor Question #7:
This item is still under internal discussion.

Labeling:

Sponsor Question #8:
We assume sites will need to provide labels with ISBT e-codes for PAS 3 platelets with qualifiers for subsequent processing of those platelets. Does FDA agree??

FDA Response to sponsor Question #8:
FDA Agrees. Please note that regulations require that appropriate labels are submitted with a licensure application.

Sponsor Question #9:
ICCBBA currently has a proposal on the table for nomenclature of platelet additive solutions per the ISBT 128 standard that would give this solution the name PAS C. FDA has given the product the established name PAS 3. This terminology will be confusing to customers. Will there be anything we will need to add to our labeling if this proposal is passed, or will this labeling just be added by the site as described above?

FDA Response to sponsor Question #9:
We believe that Fenwal has addressed this with ICCBBA in July 2009, and this issue was resolved between them.

Sponsor Question #10:
How will sites that have not converted to ISBT labeling implement PAS 3 platelets since P-codes are no longer being issued for new products?

FDA Response to sponsor Question #10:
FDA will not comment on this. The blood centers will have to resolve this issue with the AABB committee responsible for issuing the numbers. FDA regulations only require that a barcode readable label is used.

Sponsor Question #11:
The currently approved Circular of Information specifies the volume of plasma used for platelet suspension. In PAS 3 platelets, the total storage fluid volume for platelets is the same as for platelets in plasma, but is composed of 65% PAS 3 and 35% plasma. Because PAS 3 platelets are intended for the same use as platelets in plasma, we believe the Circular of Information applies for PAS 3 platelets products. Does FDA agree?

FDA Response to sponsor Question #10:
No. The PAS stored platelet product is a separate and distinct platelet pheresis product. Fenwal should address this with the authors of the AABB/ABC/ARC Circular of Information and any of their clients that use an alternate circular of information.